

(i) inserting a desired differentiated pig CICM cell or cell nucleus into an enucleated pig oocyte, under conditions suitable for the formation of a nuclear transfer (NT) unit;

(ii) activating the resultant nuclear transfer unit;

and

(iii) transferring said NT unit into the uterus of a female pig and permitting the NT unit to develop into a fetal pig.

100. The method according to claim 99, which comprises culturing said activated nuclear transfer unit until greater than the 2-cell developmental stage.

101. A fetal pig obtained according to the method of claim 99.

### REMARKS

This Reply is responsive to the Office Action dated August 21, 2002. Claims 2, 4, 18, 21, 25, 26, 36-46, 63, 64, and 78 are canceled; claims 1, 19, 20, 22-24, 27, 28, 50, 57, 61, 65-68, 70-73, 75 and 77 are amended; and new claims 79-101 are added. Entry of the foregoing and reconsideration on the merits is respectfully requested. The new claims are added pursuant to the Examiner's suggestion to separate claims directed to methods for cloning a full term pig from methods for producing a fetal pig. No new matter is added.

### Rejections of claims for obviousness-type double-patenting:

The claims were rejected for obviousness-type double-patenting over claims of U.S. Patent No. 5,945,577; of U.S. Patent No. 6,215,041; of U.S. Patent No. 6,235,069; and of U.S. Patent No. 6,235,070 B1. A terminal disclaimer is submitted herewith that disclaims patent term re: these four patents. Withdrawal of the obviousness-type double-patenting rejections is respectfully requested.

**Rejections of claims under 35 U.S.C. §112, first paragraph:**

The claims were rejected under 35 U.S.C. §112, first paragraph, as being enabled only for the claimed method wherein multiple NT units are transferred into the uterus of a female pig and permitting to develop into a fetal or full term pig.

Claims 1, 24, 50, 57, and 61 are amended to recite that the limitation of transferring the NT unit into the uterus of a female pig and permitting the NT unit to develop into a fetal or full term pig. The Applicants respectfully traverse the requirement that the claims recite transferring multiple NT units in order to produce the claimed animals. As noted in the cited article by Prather, at the time the application was filed, implantation of four or more embryos was known to be a step in the successful production of piglets by implanting embryos in female pig. However, the application does not need to teach and claim all that was known in the art as being important for successful operation of the claimed invention. As stated in the M.P.E.P., "35 U.S.C. 112 requires the specification to be enabling only to a person "skilled in the art to which it pertains," and, "[i]n general, the pertinent art should be defined in terms of the problem to be solved rather than in terms of the technology area... for which the invention is used. (M.P.E.P. § 2164.05(a), citations omitted). The specification addresses problems relating to producing a cloned embryo capable of being implanted and developing into a cloned fetal or full term pig. Persons skilled in the art are able to use known methods to implant such embryos in female pigs. Such persons skilled in the art would know that in transferring cloned NT unit into a female, it should be transferred together with several additional embryos to obtain successful development. The specification refers to such methodology on page 52, which describes transferring multiple NT units into a female pig. However, one skilled in the art would also know that one or several cloned NT units could be transferred into a female together with one or more normal, non-cloned embryos. To limit the Applicants to a method wherein multiple NT units are transferred into a single female is

improper. Such a claim could be unfairly avoided by someone who transfers a single NT unit together with multiple non-cloned embryos. The Applicants therefore request that the requirement for transferring multiple NT units be canceled, and that the rejection of the claims under 35 U.S.C. §112, first paragraph, be withdrawn in view of the foregoing amendments.

**Rejections of claims under 35 U.S.C. §112, second paragraph:**

Claims 1, 2, 5, 18, 19, 29, 47, 48, 50, 52, 54, 55, 57, 59-65, and 78 were rejected under 35 U.S.C. §112, 2<sup>nd</sup> paragraph, as being indefinite.

Claims 1 and 61 are amended to remove the phrase lacking antecedent basis. The Applicants respectfully traverse the rejection of claims 47, 48, 50, 52, 54, 55, 57 and 59-65 and 78, on the grounds that the metes and bounds of these claims are clear to persons skilled in the art.

**Rejections of claims in view of the prior art:**

Product claims of the application were rejected as being inherently anticipated under 35 U.S.C. §102 or obvious under 35 U.S.C. §103(a) in view of the cited prior art references disclosing products that were not using nuclear transfer techniques. The Applicants respectfully traverse the rejection of the claims in this manner, since the product cloned embryos, fetuses, and developed animals, non-transgenic or transgenic, are inherently distinct in that they comprise cells that have allogeneic mitochondria. Such product embryos, fetuses, and developed animals are not described by the prior art of record. Accordingly, withdrawal of the rejections is respectfully requested.

The above amendment and remarks are fully responsive to the Office Action. If there are any issues remaining that need to be resolved, the Examiner is respectfully requested to contact the undersigned so that allowance of this application can be expedited.

Respectfully submitted,

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**APPENDIX**

Claims 2, 4, 18, 21, 25, 26, 36-46, 63, 64, and 78 are canceled. Claims 1, 19, 20, 22-24, 27, 28, 50, 57, 61, 65-68, 70-73, 75 and 77 are amended as shown:

1. (Amended) A method of cloning a pig, comprising :
  - (i) inserting a desired differentiated pig cell or cell nucleus into an enucleated pig oocyte, under conditions suitable for the formation of a nuclear transfer (NT) unit;
  - (ii) activating the resultant nuclear transfer unit;
  - and
  - (iii) transferring said [cultured] NT unit [to a host mammal such that the NT unit develops into a fetus] into the uterus of a female pig and permitting the NT unit to develop into a pig.
19. (Amended) [An offspring] A pig obtained according to the method of claim [2] 1.
20. (Amended) Progeny of the [offspring] pig according to claim 19.
22. (Amended) A transgenic [offspring] pig obtained according to the method of claim [4] 3.
23. (Amended) Progeny of the [offspring] pig according to claim 22.
24. (Amended) The method according to claim 1, which further comprises combining the cloned NT unit with a fertilized embryo to produce a chimeric embryo, and transferring the chimeric embryo into the uterus of a female pig and permitting the embryo to develop into a pig.
27. (Amended) [An offspring] A pig obtained according to the method of claim [25] 24.
28. (Amended) Progeny of the [offspring] pig according to claim 27.

50. (Amended) The method according to claim 48, which further comprises [developing] transferring the chimeric embryo into the uterus of a female pig and permitting the chimeric embryo to develop into a chimeric fetus.

57. (Amended) The method according to claim 55, which further comprises [developing] transferring the chimeric embryo into the uterus of a female pig and permitting the chimeric embryo to develop into a chimeric fetus.

61. (Amended) A method of cloning a pig, comprising :  
(i) inserting a desired differentiated pig CICM cell or cell nucleus into an enucleated pig oocyte, under conditions suitable for the formation of a nuclear transfer (NT) unit;  
(ii) activating the resultant nuclear transfer unit;  
and  
(iii) transferring said [cultured] NT unit [to a host mammal such that the NT unit develops into a fetus] into the uterus of a female pig and permitting the NT unit to develop into a pig.

65. (Amended) [An offspring] A pig obtained according to the method of claim [62] 61.

66. (Amended) An organ for use as an organ xenograft, which is obtained from the [offspring] pig according to claim 19.

67. (Amended) An organ for use as an organ xenograft, which is obtained from the [offspring] pig according to claim 22.

68. (Amended) An organ for use as an organ xenograft, which is obtained from the [offspring] pig according to claim 27.

70. (Amended) An organ for use as an organ xenograft, which is obtained from the [offspring] pig according to claim 65.

71. (Amended) [An offspring] A pig according to claim 19, which comprises an agriculturally useful trait.

72. (Amended) [An offspring] A pig according to claim 22, which comprises an agriculturally useful trait.

73. (Amended) [An offspring] A pig according to claim 27, which comprises an agriculturally useful trait.

75. (Amended) [An offspring] A pig according to claim 65, which comprises an agriculturally useful trait.

77. (Amended) An organ for use as an organ xenograft, which is obtained from the [offspring] pig according to claim 76.